

1 IN THE UNITED STATES DISTRICT COURT
 FOR THE EASTERN DISTRICT OF NEW YORK
2 NO. 1:12-md-02331-BMC-PK

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3
 IN RE: PROPECIA (finasteride) :
4 PRODUCTS LIABILITY LITIGATION :MDL No.2331

:

5 vs. :Honorable Brian M. Cogan
 :Magistrate Judge Peggy Kuo

6 This Document Relates to :
 ALL CASES :

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8 - - -

9 JULY 12, 2016

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11 VIDEOTAPE deposition of
12 KEITH D. KAUFMAN, M.D., taken pursuant to
13 notice, held at MORGAN LEWIS, 1701 Market
14 Street, Philadelphia, Pennsylvania,
15 beginning at 9:00 a.m., on the above
16 date, before LISA MARIE CAPALDO, RPR,
17 Registered Professional Reporter and
18 Notary Public in and for the Commonwealth
19 of Pennsylvania.

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1 reflection of adverse event reports.

2 Adverse events do not derive from the
3 questionnaire.

4 Q. Okay. So did you use -- we
5 can agree you used a sexual function
6 questionnaire in '87 and '89, right?

7 A. Yes.

8 Q. You didn't use one in '92,
9 right?

10 A. Correct.

11 Q. But you combined the data
12 for all three to report sexual adverse
13 events in the label?

14 A. That's correct.

15 None of the adverse event
16 data comes from the questionnaire. And
17 patients were always queried about
18 adverse events at every visit in all
19 three studies in a similar manner.

20 Q. Let me direct your attention
21 to the patient package insert, Page --
22 and specifically I want to direct your
23 attention to Page 13.

24 Do you have that there,

1 Doctor?

2 A. Yes.

3 Q. Okay. Under the heading,
4 what are the possible side effects of
5 Propecia, it says, starting with these
6 men, these men reported one or more of
7 the following: less desire for sex,
8 difficulty in achieving an erection, and
9 a decrease in the amount of semen. Each
10 of these side effects occurred in less
11 than two percent of men. These side
12 effects went away in men who stopped
13 taking Propecia.

14 Did I read that correctly?

15 A. That's correct.

16 Q. Okay. Now, the patient
17 package insert is actually written for
18 the user of the drug, correct?

19 A. Yes.

20 Q. Okay. So it's written in a
21 way that's not nearly as technical as the
22 actual label itself?

23 A. Yes.

24 Q. And there's an expectation

1 or a hope that men who take this drug
2 will actually get this patient's package
3 insert and read it, correct?

4 A. Yes.

5 Q. All right. And what Merck
6 was telling these men was:

7 If you get a side effect
8 from this drug related to a sexual
9 adverse event, when you stop taking the
10 drug, it will go away?

11 A. It actually says that it may
12 go away whether you continue the drug or
13 if you stop it and that it went away in
14 all men -- or in men who stopped taking
15 the drug.

16 Q. All right. That's my only
17 question.

18 It says specifically, the
19 side effects went away in men who stopped
20 taking Propecia, correct?

21 A. Because that's a true
22 statement.

23 Q. Okay. You can't get any
24 clearer than that, can you?

1 on drug in terms of what happened
2 afterwards.

3 BY MR. BECKER:

4 Q. All right. So let's look at
5 some of the clinical data you had.

6 I'm showing you what's been
7 marked as Exhibit-52.

8 Do you have that there in
9 front of you?

10 A. Uh-huh.

11 Q. This is an e-mail that we
12 went over with Dr. Round. And I'll
13 represent to you, sir, that it's dated
14 November 3rd, 2000. I know that because
15 in what's called MedData, the date
16 appears, but the date does not appear on
17 this particular e-mail.

18 A. Uh-huh.

19 Q. You know who Patrick Ruane
20 is, correct?

21 A. Yes.

22 Q. He is somebody that worked
23 with you and Dr. Round, correct?

24 A. Yes.

1 Q. And you asked him to inquire
2 into rates of sexual adverse events
3 stemming from the clinical trials at or
4 about this time period, correct?

5 A. Yes.

6 Q. All right. And he wrote
7 back to you, during years three through
8 five in the Phase III pivotal studies,
9 six patients who were taking finasteride,
10 one milligram, discontinued due to
11 drug-related sexual experiences, the AEs
12 for five patients resolved. For one
13 patient, AN 1125 from Dr. Rittmaster's
14 cite, the AE erectile dysfunction was
15 still continuing when he discontinued the
16 study. At the time of his
17 discontinuation visit, he was off therapy
18 for 66 days. It does not look like the
19 patient was contacted for resolution of
20 the AE.

21 Did I read that correctly?

22 A. Yep.

23 Q. Okay. So you had reports of
24 six men who discontinued the drug due to

1 sexual adverse experiences, outlined in
2 paragraph one here, correct?

3 A. Yes.

4 Q. Five resolved. One did not,
5 right?

6 A. At the point of last
7 contact.

8 Q. Okay. And nobody at Merck
9 made any effort to actually contact him
10 and see if that resolution occurred,
11 correct?

12 MR. MORROW: Object to the
13 form.

14 THE WITNESS: I don't
15 believe that's true.

16 BY MR. BECKER:

17 Q. Well, it says here in the
18 last sentence, it does not look like the
19 patient was contacted for resolution of
20 the AE.

21 Did I read that correctly?

22 THE WITNESS: You did, but
23 it doesn't say that the patient
24 wasn't contacted. And, in fact,

1 in other documentation about this
2 patient, I believe the reference
3 is that the patient was contacted
4 and had the adverse event present
5 at the later point of last
6 contact.

7 BY MR. BECKER:

8 Q. And when was that?

9 A. I believe that was roughly
10 six months from discontinuation of
11 medication. So it would have been a few
12 months later than the discontinuation
13 visit.

14 Q. So six months following
15 discontinuation, this patient still was
16 suffering from the adverse event,
17 correct?

18 A. The patient was still
19 reporting the adverse event.

20 Q. Okay. The second paragraph
21 goes on to note, during years three
22 through five in the Phase III pivotal
23 studies, 23 patients who were taking
24 finasteride, one milligram, experienced

1 drug-related sexual adverse experiences.
2 Of these 23 patients, the AEs for seven
3 patients were still present when they
4 discontinued/completed the study. Of the
5 16 who had AEs resolved, the AEs for
6 seven patients resolved on therapy, and
7 the AEs for nine patients resolved while
8 off therapy.

9 Did I read that correctly?

10 A. Uh-huh.

11 Q. So yet a second group of
12 patients totaling 23 people, correct,
13 that you were evaluating in this e-mail.
14 True?

15 A. Yes.

16 Q. Okay. Of those, seven
17 patients were still experiencing the
18 adverse event when they discontinued the
19 study, correct?

20 A. On drug.

21 Q. Well, it says, the AEs for
22 seven patients were still present when
23 they discontinued/completed the study,
24 correct?

1 A. Right. But when they
2 discontinue or complete the study, they
3 are generally on drug.

4 Q. Well, but when they
5 discontinue, they are no longer on the
6 drug anymore, right?

7 A. Well, the next day.

8 Q. Okay. So when did their AEs
9 go away?

10 A. I can't answer that from
11 this e-mail.

12 Q. All right. But they still
13 had them on the last day of contact,
14 right?

15 MR. MORROW: Object to the
16 form.

17 THE WITNESS: On drug,
18 presumably.

19 BY MR. BECKER:

20 Q. Okay. But the next day,
21 they are off the drug, right?

22 A. Yes.

23 Q. And you have no idea how
24 long those adverse events continued for,

1 correct?

2 MR. MORROW: Object.

3 THE WITNESS: If we don't
4 have the data, then we don't know.

5 BY MR. BECKER:

6 Q. Okay. But for the next 16
7 men, you do appear to have the data,
8 correct?

9 A. Right. But what that means
10 is that the patients achieved resolution
11 either on or off therapy while they were
12 still participating in the trial. Once
13 the trial is over, we usually lose
14 contact with the patient.

15 Q. Okay. For the second group
16 of 16, seven of the men resolved while on
17 the drug, correct?

18 A. Yes.

19 Q. And nine of the patients
20 resolved while off therapy, correct?

21 A. Correct.

22 Q. How long did it take for
23 them to resolve?

24 A. I don't know the answer.

1 I'd have to look at the spreadsheet.

2 Q. Okay. Now, it's fair to say
3 that Merck never defined the temporal
4 nexus between discontinuation and
5 resolution, correct?

6 MR. MORROW: Object to the
7 form.

8 THE WITNESS: Again, the way
9 you're asking that question, the
10 temporal nexus?

11 BY MR. BECKER:

12 Q. Well, you knew that for some
13 men, it was going to take a little bit of
14 time for the symptom to resolve, correct?

15 A. Either in the finasteride or
16 the placebo group.

17 Q. And you never defined that
18 in the label, correct?

19 A. I'm sorry. Never defined
20 what?

21 Q. You never defined, in the
22 label, whether or not -- or how long it
23 would take for these symptoms to resolve
24 upon discontinuation, true?

1 MR. MORROW: Object to form.

2 THE WITNESS: That's not in
3 the label. That's correct.

4 BY MR. BECKER:

5 Q. Okay. And is there anything
6 in this e-mail that we're looking at that
7 suggested these men were in the placebo
8 wing of the study?

9 A. The placebo wing, at this
10 time of the extension, was only five --
11 the continuous group that was on placebo
12 the whole time, that was only five
13 percent of the entire trial.

14 Q. Right. And so --

15 A. So we don't have a balanced
16 placebo group after we get through the
17 second year.

18 Q. Okay. All I'm asking is
19 this:

20 These men that are being
21 reported here, these 29 men --

22 A. Yes.

23 Q. -- they were on finasteride,
24 right?